DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 10, 2015

Pega Medical, Incorporated
Ariel R. Dujovne
President
1111 Autoroute Chomedey
Laval, Quebec
Canada H7W 5J8

Re: K143355
Trade/Device Name: The Simple Locking IntraMedullary (SLIM) System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: June 9, 2015
Received: June 11, 2015

Dear Ariel Dujovne,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143355

Device Name
The Simple Locking IntraMedullary (SLIM) System

Indications for Use *(Describe)*
The SLIM System is intended as a temporary implant for alignment, stabilization and fixation of long bones that have been surgically prepared (osteotomy) for correction of deformities, or have sustained fractures due to trauma or disease. This includes the femur, tibia, humerus, ulna and fibula of the pediatric population (child and adolescent) , and patients with small intramedullary canals affected by skeletal displasias, osteogenesis imperfecta or other bone diseases.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Tuesday, July 7th, 2015

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant :	Pega Medical Inc. 1111 Highway Chomedey Laval, Quebec, Canada, H7W 5J8 Phone : 1-877-739-5175 Fax : 1-888-258-0760
Contact Person :	Ariel R. Dujovne
Proprietary Name :	The Simple Locking IntraMedullary (SLIM) System
Common Name :	SLIM rod
Device Classification :	Class II
Classification Name :	21 CFR-888.3020 Intramedullary fixation rod
Device Product Code :	HSB
Establishment Registration Number :	9048931

Intended Use:
The SLIM System is intended as a temporary implant for alignment, stabilization and fixation of long bones that have been surgically prepared (osteotomy) for correction of deformities, or have sustained fractures due to trauma or disease. This includes the femur, tibia, humerus, ulna and fibula of the pediatric population (child and adolescent), and patients with small intramedullary canals affected by skeletal displasias, osteogenesis imperfecta or other bone diseases.

Description:
The Simple Locking IntraMedullary (SLIM) System consists of intramedullary fixation devices for use in long bones. The solid shaft and bevelled point are designed for guided insertion through the medullary canal. Anchorage of the device is achieved through a conical cortical thread for a wedged fixation in the epiphyses or cortical bone, which aims to reduce the risk of migration. Internal features, such as a hexagonal drive and an internal mechanical thread in the head of the device, allow for capture and guidance during insertion and retrieval. Additional proximal and distal locking holes provide supplementary pinning options when required. The SLIM, single-use, implants are manufactured in medical grade Stainless Steel (SS316L, ASTM F138). The rods are available in seven diameters: 2.0, 2.6, 3.2, 4.0, 4.8, 5.6 and 6.4 mm, from 80mm up to 400 mm in length.

Basis for substantial equivalent:
The Simple Locking IntraMedullary (SLIM) System is claimed to be substantially equivalent in design, indicated use and function to the following predicate devices:

1. Stainless Steel Elastic Intramedullary Nail System [K081452] Synthes (Usa)
2. Pediflex Flexible Nail System [K082375] Orthopediatrics
3. Fassier-Duval Telescopic IM System [K041393] Pega Medical Inc.

Summary of Technologies:
The technological characteristics of the Simple Locking IntraMedullary (SLIM) System are the same or similar to the ones of the predicate devices.

Non-clinical Performance Data:
The mechanical properties of the SLIM system were calculated and compared to the properties of the Synthes SS Elastic Intramedullary Nail System [K081452]. According to the results obtained, the SLIM system's mechanical properties are superior to that of the Synthes SS Elastic Intramedullary Nail System. Four-point bending bench testing in static and fatigue on the SLIM System and STEN System confirmed these calculations. Results of the static and fatigue four-point bending bench testing on the SLIM and STEN system have demonstrated that the SLIM system performed equivalently as the predicate STEN system."

Finally, a systematic search of the scientific literature was carried out and a Clinical Evidence review report was issued. This report intended to identify and analyze the published peer-reviewed scientific literature regarding the use of intramedullary rods in general, and more specifically of the two predicate systems, in order to establish the safety and effectiveness of the Simple Locking IntraMedullary (SLIM) system by addressing the clinical hazard identified in the device Risk Analysis. As per the findings of the bench testing and the scientific literature review, the data supports the use of this product as safe and effective for its intended use; the anticipated benefits of such a system clearly outweigh the possible residual risks.

Clinical Performance Data:
No clinical testing is provided as a basis for substantial equivalence.

Conclusion:
Based on the similarities ain the intended use, design, materials, manufacturing methods, and packaging, The Simple Locking IntraMedullary (SLIM) System has been established as substantially equivalent to the previously cleared predicate devices. Furthermore, mechanical evaluation results demonstrate that the proposed SLIM System is substantially equivalent to the predicate devices.